

COMMENTS

Claims 5, 7, 8, 11-22 and 42-44 are allowed. Claims 7, 8, 11-13, 42-44 ultimately depend from claim 5, which recites:

5. A composition, comprising:
glycine; and
a) an amino acid selected from the group consisting of a beta-alanine, an ester of a beta-alanine, and an amide of a beta-alanine, or
b) a di-peptide selected from the group consisting of a beta-alanine di-peptide and a beta-alanylhistidine di-peptide.

Claim 16 depends from claims 14 of 15, which recite:

14. A composition comprising at least 0.2, 0.3, 0.4, 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5 or 5 grams of a peptide or an ester comprising a beta-alanine per dosage.
15. A composition comprising at least 0.2, 0.3, 0.4, 0.5, 1.0, 1.5, 2.0, 2.5, 3.0 grams of a peptide or an ester comprising a beta-alanine in an injectable form per dosage.

Claims 19-22 ultimately depend from claim 18, which recites:

18. A composition for humans comprising at least 200, 250, 300, 450, 500, 550, 600, 650, 700, 750 or 800 mg of a beta-alanine per dosage.

In the Examiner's Comments in the Notice of Allowability, mailed May 30, 2008, the Examiner stated that none of the references contain subject matter that alters the Examiner's previous determination that claims 5, 7, 8 and 11-22 are allowable.

Applicant recognizes that in accordance with M.P.E.P. § 1302.14, the Examiner's reasons for allowance need not set forth all of the details why the claims are allowed. In the above-referenced application, Applicant does not concede that the Examiner's stated reasons for allowance are the only reasons for which the claims are allowable. For example, none of the art of record, singly or in any combination thereof discloses, teaches or suggests a composition including glycine and an amino acid selected from the group consisting of a beta-alanine, an ester of a beta-alanine, and an amide of a beta-alanine, or a di-peptide selected from the group consisting of a beta-alanine di-peptide and a beta-alanylhistidine di-peptide, formulated for oral, enteral or parenteral administration, or formulated for infusion through the skin of a subject, or formulated as a topical cream or a patch.

In addition, each of claims 5, 7, 8, 11-22 and 42-44 is allowable on its own merits.

OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTION

In a non-final Office Action, mailed September 21, 2007, claims 5, 8, 11-13 and 18-20 were rejected as over the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-31 of U.S. Pat. No. 6,426,361. The Examiner alleged that:

although the conflicting claims are not identical, they are not patentably distinct from each other because from one construct of the patented claims, the instantly claimed elements in the form of a composition, would have been obvious. Said elements being beta-alanine, insulin and optionally a carbohydrate and/or creatine."

A Terminal Disclaimer was not filed. In the subsequent Office Action, the claims were deemed allowable, indicating that the rejection was withdrawn.

As between any of the allowed claims and claims 22-31 of U.S. Pat. No. 6,426,361 (the '361 patent), obviousness-type double patenting does not exist. The issue for obviousness-type double patenting is whether a claim in a later filed application extends a right of exclusivity granted in an earlier patent. To assess obviousness-type double patenting, the claims at issue are compared to the claims of the patent. If there is no overlap between the claims at issue and the claims of the patent, obviousness-type double patenting does not exist. If there is overlap, then, if the claims at issue embrace the claims of the patent, there is obviousness-type double patenting. If the claims at issue do not embrace the earlier issued claims, then the issue is whether, based upon the principles of claim interpretation, the claims at issue are suggested by the claims of the patent. Where the claims of the patent include no recitation of elements in the claims in the application, there should be no obviousness-type double patenting because there is no suggestion of the claimed subject matter.

Claims 5, 8 and 11-13

Allowed claims 5, 8 and 11-13 recite a composition that includes glycine and a) an amino acid selected from the group consisting of a beta-alanine, an ester of a beta-alanine, and an amide of a beta-alanine, or b) a di-peptide selected from the group consisting of a beta-alanine di-peptide and a beta-alanylhistidine di-peptide. Claims 22-27 of the '361 patent recite a composition including a mixture of insulin and a composition comprising an amino acid or an active derivative thereof selected from the group consisting of a beta-alanine, an ester of a beta-alanine and an amide of a beta-alanine.

There is no insulin in the instant claims and there is no glycine in the patented claims. Thus, there is no overlap between claims 5, 8 and 11-13 and claims 22-27 of the '361 patent. Because there is no overlap between the claims at issue and the claims of the patent, obviousness-type double patenting does not exist as between instant allowed claims 5, 8 and 11-13 and claims 22-27 of the '361 patent.

Claims 18-20

Allowed claims 18-20 recite a composition for humans that includes at least 200, 250, 300, 450, 500, 550, 600, 650, 700, 750 or 800 mg of a beta-alanine per dosage. Claims 22-27 of the '361 patent recite a composition that can include a mixture of insulin and beta-alanine. There is no limitation on the amount of beta-alanine in the composition of claims 22-27 of the '361 patent. Thus, there is overlap between the instant claims and claims 22-27 of the '361 patent. Since there is overlap, then, the question is whether the claims at issue embrace the claims of the patent. If the claims at issue embrace the claims of the patent, there may be obviousness-type double patenting. In this instance, the instant claims **do not** embrace the claims of the patent. There are embodiments of claim 22 of the '361 patent that are not encompassed by instant allowed claims 18-20. For example, an embodiment that includes 150 mg or 1000 mg beta-alanine per dosage would not be within the scope of instant claims 18-20. Thus, the allowed claims at issue do not encompass the claims of the '361 patent.

Since the claims at issue do not embrace the earlier issued claims, then the issue is whether, based upon the principles of claim interpretation, the claims at issue are suggested by the claims of the patent. Where the claims of the patent include no recitation of elements in the claims in the application, there is no obviousness-type double patenting because there is no extension of a right of exclusivity. None of claims in the issued '361 patent recite specific weights of beta-alanine or suggest such limitation.

In addition, the composition of claim 22 of the '361 patent contains insulin. Claims 23-27 of the '361 patent are dependent on claim 22 and require inclusion of insulin as an ingredient. None of the instant claims recite that insulin is an ingredient, and, thus, cannot suggest such species as an ingredient. Hence, there is no extension of a right of exclusivity. Further, there is no suggestion based upon the rules of claim construction that would result in the species claimed in the '361 patent. Thus, the claimed subject matter in the instant application is not merely an obvious variation of the subject matter of claims 22-31 of the '361 patent. Although both compositions include beta-alanine, the compositions are different. It would not be obvious to one of ordinary skill in the art in view of claims 22-31 of the '361 patent, which can include insulin and beta-alanine, to arrive at a composition that includes at least 200, 250, 300, 450, 500, 550, 600, 650, 700, 750 or 800 mg of a beta-alanine per dosage.

Further, the instant claims are not generic to claims 22-31 of the '361 patent. Claim 18 and its dependent claims are directed to compositions that includes at least a specified

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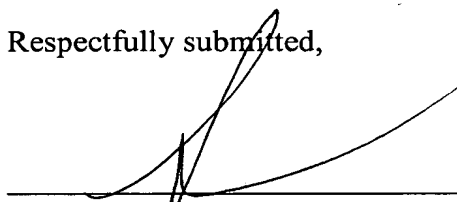
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Comments on Examiner's Reasons for Allowance

amount of a beta-alanine per dosage. Claims 22-31 of the '361 patent do not specify an amount of beta-alanine, and hence are more generic in this aspect. The claims of the '361 patent do not mention or call out the species of specific weights of beta-alanine as instantly claimed. Thus, obviousness-type double patenting does not exist as between instant allowed claims 18-20 and claims 22-27 of the '361 patent.

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Entry of these remarks into the file history of the above-captioned application respectfully is requested.

Respectfully submitted,



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